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10/712,763	11/12/2003	Barry James Maurer	54652.8013.US00	7398

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,763	MAURER ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☒ Claim(s) *13,22,25 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-32 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the application.

Priority

The instant application does not claim priority to any prior filed U.S. or foreign applications. As such, the earliest effective U.S. filing date of the application is November 12, 2003.

Claim Objections

Claims 13, 22, 25 and 27 are objected to because of the following informalities: it appears the word "consisting" in line 2 of each claim should be ---consists---. Appropriate correction is required.

Claim Rejections - 35 USC § 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-9, 15-18 and 24-30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, one of the compounds being administered is only described with respect to its intended action, in this case, a compound that generates ceramide (*i.e.* "a ceramide-generating anticancer agent"). The instant disclosure lacks adequate written description for such a broad genus. For example, page 7, lines 5-7 of the specification describes a ceramide-generating anticancer agent as "any agent or treatment that directly or indirectly results in the increase or generation of ceramide." Some dependent claims limit the ceramide-generating agent to "a ceramide generating retinoid comprising a retinoic acid derivative" (*e.g.* instant claim 4). However, this genus also lacks adequate written description in the specification. There is only one example provided in the specification of such a retinoic acid derivative, namely, fenretinide (4-HPR) (page 12, lines 3-5).

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." While the specification describes a single species of the instantly claimed "a ceramide-generating anticancer agent" at page 12, lines 3-5 and page 14, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by "a ceramide-generating anticancer agent" or "a ceramide generating retinoid comprising a retinoic acid

derivative". Therefore, only the single disclosed species, fenretinide (4-HPR), but not the full breadth of the claims, meets the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 1-2, 7, 15-16 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to administration of a "ceramide degradation inhibitor". Some dependent claims further limit said inhibitor to compounds that are "effective in inhibiting glucosylceramide synthase and 1-O-acylceramide synthase." Compounds that inhibit glucosylceramide synthase and 1-O-acylceramide synthase, as described in the specification, can include any compound capable of inhibiting both of these enzymes simultaneously. Thus, the claims are drawn to administration of a genus of compounds that is defined only by biological activity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of the complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is that the compounds inhibit ceramide degradation as well as glucosylceramide synthase and 1-O-acylceramide synthase. There is no description of structural characteristics that are required to

retain biological activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed *supra*, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of compounds that: a) inhibit ceramide degradation; b) inhibit glucosylceramide synthase; and c) inhibit 1-O-acylceramide synthase, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or synthesizing it (it is noted, however, that no such methods have been disclosed). The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the single disclosed species, D-threo-PPMP, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes it clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see *Vas-Cath* at page 1115). See also *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be

sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement).

Claims 1-2, 5-6, 9-27 and 29-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, the claims recite administration of compounds "or esters thereof." The instant disclosure lacks adequate written description for esters of the claimed compounds. Nowhere does the specification provide any description of structural characteristics, methods of making, or methods of isolating any esters of the recited compounds.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." As stated supra, the specification provides the skilled artisan with no description of how to make, isolate, or identify any esters of the claimed compounds.

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 17-32 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1, 7, 12, 24 and 28 recite methods of "treating a hyperproliferative disorder." The claims are indefinite because it is not clear: a) to who or what the method is intended to treat and b) to who or what the recited compounds are being administered. The preamble of the claim is not so linked to the body of the claim to make it is sufficiently clear that the administration of the recited compounds is treating the condition recited in the preamble. Claims dependent from claims 1, 7, 12, 24 and 28 are included in this rejection.

Claims 3, 8, 13, 17, 21, 22, 24-27 and 29 recite the compound "D-threo-PPMP". This limitation is indefinite because the first recitation of an abbreviation in the claims (in this case, claim 3) must include the full recitation of the abbreviated name. Claims dependent from claims 3, 8, 13, 17, 21, 22, 24-27 and 29 are included in this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15-21, 24 and 26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Maurer *et al.* (U.S. Patent No. 6,352,844; Issued March 5, 2002).

The '844 patent teaches methods of treating hyperproliferative disorders comprising administration of: a) a ceramide-generating retinoid; and b) a ceramide-degradation inhibitor (Abstract; Claims). Said ceramide-generating retinoid is preferably fenretinide or a pharmaceutically acceptable salt thereof (col. 9, lines 16-25; Claims 4, 7, 11 and 14). Said ceramide-degradation inhibitor can be a glucosylceramide synthesis inhibitor, including 1-phenyl-2-palmitoylamino-3-morphilino-1-propanol (PPMP) (col. 9, line 61 to col. 10, line 28). Inhibition of 1-O-acylceramide synthase as required in the instant claims would be inherent in the methods disclosed in '844 when PPMP is administered as the ceramide-degradation inhibitor. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Further, instant claims wherein the ceramide degradation inhibitor "comprises D-threo-PPMP" are anticipated by the reference because the claimed isomer is present in the methods described in the '844 patent. The ceramide-generating retinoids are given in amounts effective to produce necrosis, apoptosis, or both in the tumor and the ceramide-degradation inhibitor is administered in an amount effective to increase necrosis or apoptosis or both in the tumor (Claims). The active compounds described in the '844 patent (namely ceramide-generating retinoids and ceramide-degradation inhibitors) can be formulated for administration in a single pharmaceutical carrier and may be administered orally, topically and intravenously (col. 14, lines 11-15 and 33-42).

Thus, the '844 patent teaches all of the limitations of the instant claims.

Claims 1-12, 15-21, 24, 26 and 28-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by Maurer *et al.* (U.S. Patent No. 6,368,831; Issued April 9, 2002).

The '831 patent teaches methods of treating hyperproliferative disorders comprising administration of: a) a ceramide-generating retinoid; and b) a ceramide-degradation inhibitor (Abstract; Claims). Said ceramide-generating retinoid is preferably fenretinide or a pharmaceutically acceptable salt thereof (col. 8, lines 51-60; Claims 4, 7, 11, 14 and 25). Said ceramide-degradation inhibitor can be a glucosylceramide synthesis inhibitor and/or 1-acylceramide synthase inhibitor, including 1-phenyl-2-palmitoylamino-3-morphilino-1-propanol (PPMP) (col. 9, lines 25-63). PPMP is disclosed to inhibit both glucosylceramide synthesis inhibitor and 1-acylceramide synthase (col. 22, line 59 to col. 23, line 45). The diasteriomer, D,L-threo-PPMP, is taught to inhibit both glucosylceramide synthesis and 1-O-acylceramide synthase and significantly increase the cytotoxicity of fenretinide (col. 23, lines 2-45). Further, instant claims wherein the ceramide degradation inhibitor "*comprises* D-threo-PPMP" are anticipated by the reference because the claimed isomer is present in the methods described in the '831 patent. The ceramide-generating retinoids are given in amounts effective to produce necrosis, apoptosis, or both in the tumor and the ceramide-degradation inhibitor is administered in an amount effective to increase necrosis or apoptosis or both in the tumor (Claims). The active compounds described in the '831 patent (namely ceramide-generating retinoids and ceramide-degradation inhibitors) can be formulated for administration in a single pharmaceutical carrier and may be administered orally, topically and intravenously (col. 13, lines 34-36 and 54-62).

Thus, the '844 patent teaches all of the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 13-14, 22-23, 25 and 27 are rejected under 35 U.S.C. § 103(a) as being obvious over Maurer *et al.* (U.S. Patent No. 6,368,831; Issued April 9, 2002) in view of Abe *et al.* (Journal of Lipid Research, 1995, vol. 36, pages 611-621).

The '831 patent discloses methods and formulations for treating hyperproliferative disorders comprising administration of: a) a ceramide-generating retinoid; and b) a ceramide-degradation inhibitor (Abstract; Claims). Said ceramide-generating retinoid is preferably fenretinide or a pharmaceutically acceptable salt thereof (col. 8, lines 51-60; Claims 4, 7, 11, 14 and 25). Said ceramide-degradation inhibitor can be a glucosylceramide synthesis inhibitor and/or 1-acylceramide synthase inhibitor, including 1-phenyl-2-palmitoylamino-3-morphilino-1-propanol (PPMP) (col. 9, lines 25-63). PPMP is disclosed to inhibit both glucosylceramide

synthesis inhibitor and 1-acylceramide synthase (col. 22, line 59 to col. 23, line 45). The diasteriomer, D,L-threo-PPMP, is taught to inhibit both glucosylceramide synthesis and 1-O-acylceramide synthase and significantly increase the cytotoxicity of fenretinide (col. 23, lines 2-45). The ceramide-generating retinoids are given in amounts effective to produce necrosis, apoptosis, or both in the tumor and the ceramide-degradation inhibitor is administered in an amount effective to increase necrosis or apoptosis or both in the tumor (Claims). The active compounds described in the '831 patent (namely ceramide-generating retinoids and ceramide-degradation inhibitors) can be formulated for administration in a single pharmaceutical carrier and may be administered orally, topically and intravenously (col. 13, lines 34-36 and 54-62).

The instant claims differ from the reference in that they recite methods and formulations wherein the ceramide degradation inhibitor *consists essentially of* D-threo-PPMP. The '831 patent does not disclose this enantiomer of PPMP, although it does disclose the racemic diastereomer, D,L-threo-PPMP.

However, Abe *et al.* disclose analogs and homologs of PDMP that inhibit glucosylceramide synthase have the *R,R*-(D-threo)-configuration. D-threo-PPMP is disclosed in Table 1 (page 614). When enantiomers of PDMP and PPMP were compared it was found that PPMP improved the inhibitory activity against glucosylceramide synthase (page 614, right column, first full paragraph).

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed methods and formulations wherein the ceramide degradation inhibitor consists essentially of D-threo-PPMP would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The '831 patent discloses that D,L-

threo-PPMP inhibits both glucosylceramide synthesis and 1-O-acylceramide synthase and significantly increases the cytotoxicity of fenretinide (col. 23, lines 2-45). Abe *et al.* disclose the instantly claimed enantiomer and further disclose that it is this enantiomer that is the more effective inhibitor of glucosylceramide synthase. Further, the '831 patent discloses that the D enantiomer of glucosylceramide synthesis and 1-O-acylceramide synthase inhibitors are preferred.

Thus, the skilled artisan would be imbued with at least a reasonable expectation that one isomer of D,L-threo-PPMP may be more effective than the other and would have been motivated to isolate the individual enantiomers of the compound demonstrated to be effective in the '831 patent (D,L-threo-PPMP) and, through routine experimentation, determine which is the more effective inhibitor in the claimed methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 15-21, 24 and 26-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 20-23 of U.S. Patent No. 6,368,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed methods are commensurate in scope and administer the same compounds as the methods claimed in the '831 patent. For example, '831 discloses that D,L-threo-PPMP inhibits both glucosylceramide synthesis and 1-O-acylceramide synthase and significantly increases the cytotoxicity of fenretinide (col. 23, lines 2-45). Both the instant claims and the claims of '831 recite administration of PPMP and fenretinide to treat the same hyperproliferative disorders. Further, the instantly claimed formulations would have been obvious because the method claims of the '831 patent require administration of said formulations.

Claims 1, 4-6, 12, 15, 21, 23, 24 and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,352,844. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed methods are commensurate in scope and

administer the same compounds as the methods claimed in the '844 patent. For example, both '844 and the instant claims recite methods of treating hyperproliferative disorders (including tumors) by administering a ceramide-generating retinoid (*e.g.* fenretinide) and a ceramide degradation inhibitor (*e.g.* PPMP). Further, the instantly claimed formulations would have been obvious because the method claims of the '844 patent require administration of said formulations.

Other Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 1) Maurer, *et al.*, J. Natl. Cancer Inst., 2000, vol. 92, pages 1897-1909; 2) O'Donnell, *et al.*, Leukemia, 2002, vol. 16, pages 902-910; and 3) Litvak *et al.*, J. Gastrointest. Surg., 2003, vol. 7, pages 140-148.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

September 12, 2006

Ardin H. Marschel 9/16/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER